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Report Highlights:

In early 2013, the Hong Kong government announced its intention to regulate genetically engineered (GE) food by introducing a mandatory pre-market safety assessment scheme in Hong Kong. While consultation is to be launched in late 2013, there is no timeframe when this mandatory pre-market safety assessment will be implemented. Hong Kong continues to adopt voluntary labeling guidelines for GE products.

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Section I. Executive Summary

Hong Kong is one of the U.S.'s fastest growing major agricultural export markets. Ranking as the 6th largest market in 2012, total U.S. agricultural exports reached a record \$3.69 billion. Within that total, Hong Kong ranked as the 4th largest market for U.S. high-value consumer-ready food and beverage exports totaling \$3.16 billion in 2012. In the first 4 months of 2013, U.S. high-value consumer-ready agricultural exports to Hong Kong reached \$794 million.

The most recent development of Hong Kong's biotechnology policy has been Hong Kong's move towards mandatory pre-market safety assessment scheme for GE foods. The Hong Kong government (HKG) is planning to launch public consultation in 2013 while there is no mentioning of any implementation timeframe. According to the available information, the application for assessment is to be done by biotechnology companies. Therefore, there should be no impact on individual U.S. exporters and trade.

While there are voices in certain sectors of the community such as consumer and green groups calling for mandatory labeling of GE foods, the HKG has ruled out such an initiative at the moment on the grounds that there is no international consensus. Instead, the government encourages the trade to comply with the voluntary guidelines which were introduced in 2006.

The HKG started to implement its Genetically Modified Organisms (Control of Release) Ordinance and the Genetically Modified Organisms (Documentation for Import and Export) Regulation in September 2011 in order to observe the Cartagena Protocol on Biosafety. The Ordinance and Regulation stipulate import documentation requirements for products containing living modified organisms (LMOS). Also, prior approvals are required for products containing LMOs which are intended to be released into the environment. U.S. agricultural and food exports to Hong Kong are not impacted because there are minimal, if any, U.S. exports of LMOS to Hong Kong for release into the environment.

In connection with the Ordinance is the establishment of the Genetically Modified Organisms Register which lists the application and approval status of LMOs intended to be released into the environment. The Register shows no production of GE plants and animals in Hong Kong. However, GE papaya is grown in Hong Kong. Given the prevalence of GE papaya production in backyard farms, this GE crop

is exempt from the application and approval requirements of the Genetically Modified Organisms (Control of Release) Ordinance. Therefore, GE papaya, though planted in Hong Kong, is not listed on the Register.

Table 1. Hong Kong: U.S. Agricultural Exports to Hong Kong in 2012

Products	US\$ million	% of U.S. total exports	Ranking
All Agricultural, Fish & Forestry	3,685	2.30	6
HS1005 Corn (Maize)	6.8	0.07	31
Soybeans	1.8	0.01	35
Sub-total	8.6		
All Consumer-Oriented food products	3,156	5.01	4

Source: Global Trade Atlas – U.S. Department of Commerce, Bureau of Census

Section II: Plant and Animal Biotechnology

Chapter 1: Plant Biotechnology

Part A: Production and Trade

a) Product Development:

Hong Kong carries out research on GE rice at the Chinese University of Hong Kong, although field trials are conducted in China. Professor Samuel Sun, in co-operation with the National China Hybrid Rice Research & Development Center, conducts research to improve the quality and nutritional value of super hybrid rice by utilizing transgenic plant production methods. According to Professor Sun, 50 percent of rice produced in China is of hybrid type, which has a yield that is 30 percent higher than conventional rice. Professor Sun's research project is to improve the lysine content of the super hybrid rice.

b) Commercial Production:

Hong Kong does not commercially produce any biotechnology crops, nor does it conduct field trials. (However, there is some backyard production of GE papayas.) Farming is insignificant in Hong Kong. Total land use for vegetables, flowers, field crops, and orchards are 297 hectares, 147 hectares, 19 hectares and 272 hectares respectively in Hong Kong. In 2012 agricultural production amounted to \$98 million, comprising \$32 million in crop production, \$35 million in livestock production and \$32 million in poultry production. Hong Kong's agricultural production remains stable but there is no likelihood that it will expand.

In the past decade, the HKG has promoted organic farming as a niche market for Hong Kong's farmers so that they could compete to grow vegetables amidst the severe competition from lower priced conventional and organic imports from Mainland China. In an effort to promote this niche industry and

support the development of organic farming, an organic certification program, through the Hong Kong Organic Resource Center (HKORC), was established in 2002. Since 2004, the HKORC has provided independent organic certification services to farmers and food processors. By the standard of HKORC, all certified organic products are GE free.

c) Exports:

Hong Kong does not export any GE crops.

d) Imports:

On the trade front, the few soybean users in Hong Kong require non-GE soybeans because of market-driven factors; for example, their processed products are exported to overseas markets demanding GE free ingredients. Buyers generally have a perception that all U.S. soybeans are of GE origin. Some users of soybeans for processing report that Canadian Special Quality White Hilum (SQWH) grade soybean is popular among Hong Kong buyers. However importers claim that while SQWH soybeans are non-GE there is no identity preservation. In 2012, Canada accounted for 92 percent (\$22 million) of Hong Kong's soybean market while the U.S. merely for a share of 0.2 percent (\$47,535)¹.

Survey Reflecting Importation and Production of GE crops

The Agriculture, Fisheries and Conservation Department (AFCD) conducted a survey between 2011-2012 drawing 978 crop samples from markets and farms to assess the presence of GE ingredients in crop supplies, of which 194 samples were found with GE ingredients. Of these 194 samples, papaya accounted for 184 samples or 95 percent. Of these 184 GE papaya samples, 144 came from a pool of 467 local produce samples, 39 from a pool of 107 imported produce samples and 1 from a pool of 83 seed samples. The imported GE papayas claimed to be imported from China, the U.S and Fiji whereas the GE papaya seed from Hawaii.

The remaining 10 GE samples included animal feed (from Germany and Poland) and Zebra fish (country of origin unknown).

The table below depicts the summary of the survey result.

	No. of Tested Samples	No. of Positive Samples	Species of Samples with Positive Result
Imported Fruit	107	39	Papaya
Imported Vegetables	200	0	
Other Imported Food & Feed	93	2	Animal Feed
Seeds	83	1	Papaya
Local Produce	467	144	Papaya
Ornamental Flowers and Aquarium Fish	28	8	Zebra Fish
Total	978	194	Papaya, Animal Feed,

¹ Global Trade Atlas – Hong Kong Census & Statistics Department

	Zebra Fish

Source: Hong Kong Agriculture, Fisheries and Conservation Department

As AFCD is responsible for agriculture and fisheries in Hong Kong, the survey does not cover any processed foods such as breakfast cereals and chips.

e) Food Aid Recipient Countries:

Hong Kong is not a food aid recipient and is unlikely to be a food aid recipient in the future.

Part B: Policy

a) Regulatory Framework:

The Food and Health Bureau (FHB) is responsible for the policy direction in regards to biotech foods. The Food and Environmental Hygiene Department (FEHD) is the Bureau's department for food safety, which administers its programs through its Center for Food Safety. Administration of policies relating to agricultural production falls under the portfolio of the Agriculture, Fisheries and Conservation Department (AFCD) within FHB.

Pre-Market Safety Assessment Scheme

A recent development of Hong Kong's biotechnology related policy is HKG's announcing its intention to regulate GE food by introducing a mandatory pre-market safety assessment scheme. According to the proposed regulatory framework, a GE food developer would need to apply to the HKG if any food products containing its GE ingredients are to be sold in Hong Kong. The GE food developer is required to submit an application and provide supporting documentation to the Center for Food Safety for evaluation in the context of Codex principles and guidelines. GE food which consists of, or is designed from, GE microorganisms, plants and animals, must pass the safety assessment before it may be sold in Hong Kong.

As it is the GE food developer who will be responsible for preparing the pre-safety assessment applications, which in general have already been prepared for many other markets, Hong Kong's adoption of a similar measure should not pose any significant barriers on trade.

The Center for Food Safety has not decided whether any application fee will be charged.

The HKG has pledged that they will devise a suitable transitional arrangement for GE food that is already on the market when the pre-market safety assessment scheme becomes effective. Once the scheme is in operation, there is a designated website listing the Hong Kong approved GE foods and food manufacturers and importers will be responsible to ensure that their products contain only approved GE foods.

The HKG is planning to launch public consultation in 2013 but there is no timeframe for legislative process.

More details of the pre-market safety assessment scheme are provided in a previous Gain Report.

Ordinance and Regulation Implementing the Cartagena Protocol on Biosafety

Hong Kong started to implement its Genetically Modified Organisms (Control of Release) Ordinance and the Genetically Modified Organisms (Documentation for Import and Export) Regulation in March 2011 with a six- month grace period which ended on August 31, 2011. The HKG introduced the new law in order to implement measures set forth under the Cartagena Protocol on Biosafey. China has been a party to the Convention and the Protocol since 1993 and 2005 respectively. They are now extended to Hong Kong with the implementation of the new law.

There have not been any reported cases that the new regulation has posed any trade barriers on U.S. food and agricultural exports to Hong Kong.

The Ordinance stipulates that the production and importation of LMOs to Hong Kong (except for exemptions provided by the Exemption Notice) with the intention to be released into the environment requires to obtain prior approval from the Agriculture, Fisheries and Conservation Department. (Note: GMO in the Ordinance refers to living modified organisms.) The AFCD maintains a LMO online register which keeps non-confidential information received pertaining to the LMO approval applications. As of June 2013, the HKG has not received any such application yet.

Under the new law, there are prescribed documentation requirements for all shipments containing LMOs. The HKG emphasized that the documentation requirements adhere strictly to the requirements stipulated by the Cartagena Protocol.

According to the subsidiary regulation, documentation is required for the following categories of LMOs:

- a) LMOs intended for direct consumption as food, feed or for processing; (LMOs-FFP)
- b) LMOs intended for contained use; and
- c) LMOs intended for release into the environment.

The following paragraphs summarize the information required for LMO shipments for various purposes.

For LMOs-FFP

- If the identity of the LMO is known, the shipment contains such a LMO; if the identity of the LMO is not known, the shipment may contain such a LMO;
- The LMO is not intended for release into the environment;
- The common name, scientific name and, where available, commercial name of the LMO;
- The transformation event code of the LMO or, where available, its unique identifier code; and,
- The details of the importer or exporter (such as name, address and contact information) for further information.

For LMOs intended for contained use

- The shipment contains a LMO which is intended for contained use;
- The common name, scientific name and, where available, commercial name of the LMO;
- The name, address and contact details of the consignee and the exporter or importer;
- The requirement, if any, for the safe handling, storage, transport and use of the LMO. If there is no requirement as stated above, a statement that there is no such requirement; and
- New or modified traits or characteristics of the LMO such as event of transformation, risk class, specification of use, and any unique identification, where available, as a key to accessing information in the Biosafety Clearing-House.

For LMOs intended for release into environment

- The shipment contains a LMO;
- The common name, scientific name and, where available, commercial name of the LMO;
- The traits and characteristics of the LMO, including transgenic traits and characteristics such as event of transformation or, where available, a reference to a system of unique identification;
- The requirement for the safe handling, storage, transport and use of the LMO under applicable existing international instruments, local legislation or any agreement entered into by the exporter or importer;
- If there is no requirement as stated above, a statement that there is no such requirement;
- The name, address and contact details of the exporter or importer;
- The details of contact point for further information, including an individual or organization in possession of information, in case of emergency;
- The risk class and import approval for the first transboundary movements of the LMO; and,
- A declaration that the movement of the LMO is in conformity with the requirements of the Protocol and which is applicable to the exporter.

There is no specific requirement regarding the form of documentation accompanying LMO shipments. The use of a commercial invoice or other documents required or utilized by existing documentation systems, or documentation as required by other local legislation and / or administrative frameworks is acceptable as documentation that should accompany the LMO shipments. Such documentation should include the information specified in the paragraphs above (as the case may be) and allow for easy recognition, transmission and effective integration of the information requirements. In addition to commercial invoices, other forms of documentation that are acceptable include import/export manifests; and licenses or certificates issued or required under other legislation (e.g. phytosanitary certificates).

The AFCD provides guidelines on documentation requirements and documentation samples.

Exemptions to GM Ordinance

The Genetically Modified Organisms (Control of Release) Ordinance which became effective March 2011 requires that both the local production and importation of GM crops with the intention to be released into the environment obtain approval from AFCD. Upon the expiry of the grace period, any person growing GM crops which have not been approved by the AFCD will be in violation of the law, except for exemptions provided by the Exemption Notice.

The Genetically Modified Organisms (control of Release) (Exemption) Notice made under the Genetically Modified Organisms (Control of Release) Ordinance took effect June 23, 2012. The Notice exempts all varieties of genetically engineered papaya and any LMO that is contained in a veterinary vaccine(live recombinant veterinary vaccines) from the application of an Ordinance's provision that a person must not knowingly cause a LMO to be released or maintain the life of a LMO in the environment.

The Notice also exempts two commercialized varieties of GE papaya (GE papaya with the unique identifier code of CUH-CP551-8 and GE papaya with the transformation event code of Huanong 1), and live recombinant veterinary vaccines from the application of an Ordinance 's provision that a person must not knowingly import a LMO that is intended for release into the environment.

The rationale for the exemption was that given the low risk of the exempted LMO to the local biodiversity, the exemption would avoid creating undue nuisance and disturbance to the public and cater for the need of the application of live recombinant veterinary vaccines in emergency situations such as an outbreak of a pandemic disease.

Based on a risk assessment conducted by the HKG, the GE papaya is unlikely to pose any adverse biosafety effect on the biological diversity of the local environment because papaya is an exotic species and that it does not have any close relatives in Hong Kong. As such, the release of GE papaya to the environment is unlikely to pose any risk to local biodiversity. Due to the species barrier, the inserted genes of GE papaya cannot pass on to local wild plants.

The HKG decided to exempt local papaya growers from applying for approval for releasing GE crops into the environment resulted from the wake of a survey conducted in 2010 - 2011 indicating over 44 percent of locally grown papaya are GE products. Hong Kong has little farming. Most locally produced papayas are backyard crops for self consumption with no or little commercial value. It is envisaged that many of these farmers are senior citizens living in the suburbs and may not be aware of the new ordinance. Even if they have heard of it, they might not bother to apply for approval with an application fee of over US\$1800 nor would they have the expertise to submit the necessary information such as a risk assessment of the crops.

The HKG realized that enforcement of the new law with respect to the growing of papayas would be a challenge. Therefore, they decided to provide an Exemption Notice under the new ordinance by which it will no longer be an offence for the growing of GE papayas even without obtaining the approval from the HKG.

b) Approvals:

Prior approval is required for the production and importation of LMOs which are intended to be released into the environment. All applications are provided at the <u>AFCD link</u>. As of June 2013, the AFCD has not received any such application.

c) Field Testing:

None

d) Stacked Events Approvals:

None

e) Additional Requirements:

None

f) Coexistence:

None

g) Labeling:

Labeling of GE Food Products - Voluntary Labeling Approach

There is no legislation for mandatory labeling for GE foods or feeds. The Center for Food Safety released guidelines for voluntary labeling of GE foods in 2006 in order to answer the public's call for consumers' right to make informed choices. In 2008, the HKG announced that there is no need for a mandatory labeling law in Hong Kong based on an evaluation exercise of the voluntary labeling scheme. The HKG said they are not adopting a mandatory scheme because currently there is no international consensus on mandatory labeling. Their declared position is to closely monitor international development on this issue and to promote the voluntary guidelines to the trade for more widespread adoption.

The guidelines were formulated by a working group established under the Center for Food Safety, with members coming from various sectors including manufacturing, wholesale, retail, consumer groups and government departments. The guidelines are advisory in nature and do not have any legal effect. Adoption is entirely voluntary and is not binding. The guidelines apply to prepackaged food.

The guidelines are based on the following four principals:

- The labeling of biotech food will comply with existing food legislation.
- The threshold level applied in the guidelines for labeling purpose is 5 percent, in respect to individual food ingredients.
- Additional declaration on the food label is recommended when significant modifications of the food, e.g. composition, nutrition value, level of anti-nutritional factors, natural toxicant, presence of allergen, intended use, introduction of an animal gene, etc, have taken place.
- Negative labeling is not recommended.

As the guidelines are voluntary, U.S. food exports should not be affected if they choose not to have any

GE labeling. However, it should be noted that the HKG does not encourage negative labeling when no GE counterparts of the respective products exist. Also, the HKG does not encourage negative labeling using very definite terms such as:

- GMO free.
- Free from GM ingredients, etc

For products with such definite negative labeling, the government may take the initiative to test the products against GE ingredients and a zero tolerance will be adopted for testing purposes. If products are found to have misleading labeling, a retailer may be subject to prosecution under Section 61 – False Labeling and Advertisement of Food or Drugs of <u>Chapter 132 Public Health and Municipal Services</u> Ordinance.

If the trade chooses to apply negative labeling, the government advises to use less definite terms such as "sourced from non-GM sources" (which contains less than 5 percent of GM content) and to have documentation to substantiate such declaration. For more details, please refer to <u>GAIN Report</u> HK#6026.

h) Trade Barriers:

None

i) Intellectual Property Rights:

Not applicable because Hong Kong does not commercially plant GE crops.

However, Hong Kong has intellectual property legislation covering <u>Patents</u>, <u>Registered Designs Laws</u>, <u>Copyright</u>, <u>Trade Descriptions</u>; <u>Layout-Design (Topography) of Integrated Circuits</u> and <u>Plant Varieties</u> Protection.

j) Cartagena Protocol Ratification:

China ratified the Cartagena Protocol on Biosafety in 2005. It was extended to Hong Kong on May 9, 2011 upon the implementation of the Genetically Modified Organisms (Control of Release) Ordinance and the Genetically Modified Organisms (Documentation for Import and Export) Regulation. Details of the ordinance and regulation are provided earlier under the paragraph "Regulatory Framework".

There has been no impact on trade.

k) International Treaties/Fora:

Hong Kong is a member of the World Trade Organization (WTO), Asia-Pacific Economic Cooperation (APEC) and the Pacific Economic Cooperation Council (PECC) in its own right. In addition, Hong Kong has observer status on the Trade Committee of the Organization for Economic Cooperation and Development (OECD). Hong Kong's participation in CODEX Alimentarius, the World Health Organization (WHO), World Organization for Animal Health (OIE) and Asia Pacific Plant Protection Commission is not as an individual member but as part of the China delegation.

Under Article 153 of the Basic Law, the views of Hong Kong must be sought before international agreements to which China is a party are extended to Hong Kong. China became a member of

International Plant Protection Convention (IPPC) in October 2005. Hong Kong is currently reviewing its plant quarantine measures to see if they can conform to IPPC's standards. Therefore, membership in the IPPC has not yet been extended to Hong Kong.

1) Related Issues:

None

m) Monitoring and testing:

The Agriculture, Fisheries and Conservation Department (AFCD) conducted an annual survey monitoring the importation and production of GE crops. Details was included in an earlier section under Part A, d) Imports

n) Low-Level Presence Policy:

According to the voluntary labeling guidelines of GE food products, the threshold level applied for labeling purpose is 5 percent, in respect to individual food ingredients. Details of the labeling guidelines was discussed earlier under Part B g) Labeling

In relation to the Genetically Modified Organisms (Control of Release) Ordinance and the Genetically Modified Organisms (Documentation for Import and Export) Regulation, the documentation requirements do not apply if:

- a) the LMOs are imported or exported in a lot together with other living organisms;
- b) the LMOs are unintentionally mixed with those other living organisms; and
- c) the percentage of the amount of the LMOs to the total amount of living organisms in the lot does not exceed the prescribed percentage.

The prescribed percentages are set as follows:

- 1. 5% for LMOs-FFP;
- 2. 0% for LMOs intended for contained use; and
- 3. 0% for LMOs intended for release into the environment.

Part C: Marketing

a) Marketing Acceptance:

HKG's 'green' groups, consumer organizations and a few Legislative Council (Legco) members have been advocating for mandatory labeling of GE foods for many years. Their rationale is based on consumers' "right to know". Food safety or science is not their key argument. They also expressed doubts whether the existing voluntary labeling is effectively implemented by the trade. Lobbying by green groups and consumer organizations has gained support of certain Legco members. In January 2000, Legco adopted a motion to "draw on the experience of most member states of the European Union and expeditiously legislate for a labeling system" and to "conduct strict examinations and tests" on GE foods. In June 2003, Legco passed a motion calling on the government to expeditiously establish a "voluntary first, and then mandatory" approach to a labeling system for GE foods. However, the results of motion are not binding for the HKG.

b) Public/Private Opinions:

Earlier this year, the Hong Kong Consumer Council² renewed its call for mandatory labeling for GE food in light of a survey result showing that the industry does not comply with the existing voluntary guidelines. There are products containing GE ingredients exceeding threshold level (5%) but does not carry any positive labeling as recommended by the guidelines. Also, some samples were found carrying misleading negative GE labels when the ingredients do not have any commercialized GE counterparts. A report on Consumer Council Called for Mandatory Labeling for Biotech Food is available at the <u>FAS</u> website.

The food industry has generally opposed to mandatory labeling of GE foods on the grounds that it would limit the choices of consumers, reduce variety of food supplies to Hong Kong and add burden to consumers and the industry alike. Hong Kong's retailers have said they would not import any products that carried a GE label. They believe that consumers will not choose GE products when there are other choices available.

On the whole, Hong Kong consumers are not concerned about foods containing GE ingredients. There have not been any strong actions in the general public urging the HKG to adopt mandatory labeling for GE foods in recent years. Prices, food safety and nutritional values are of bigger concern in general. However, local food processors would specify the use of non-GE soybeans particularly if their products are exported overseas.

c) Marketing Studies:

None

Part D: Capacity Building and Outreach

a) Activities:

Hong Kong government officials are regularly invited to attend APEC High Level Policy Dialogue for Agricultural Biotechnology (HLPDAB). In 2003, Hong Kong government representatives will attend the APEC Workshop on Regulatory Issues on Emerging Agricultural Technologies held in Indonesia.

b) Strategies and Needs:

Close monitoring of the government's approach to implementing its upcoming pre-market safety assessment scheme is required.

Chapter 2: Animal Biotechnology

Part E: Production and Trade

a) Biotechnology Product Development:

Animal farming is insignificant in Hong Kong. There is no genetic engineering and cloning being done on Hong Kong's limited animal farms.

² A statutory organization promoting and protecting consumer interests

b) Commercial Production:

None

c) Exports:

None

d) Imports:

Importation of transgenic animals is limited to two types of aquarium fish: zebra fish and rice fish. They are imported at a very insignificant amount as pet fish.

Part F: Policy

a) Regulation:

With the implementation of Genetically Modified Organisms (Control of Release) Ordinance, the importation of live transgenic animals, which are to be released into the environment, are required to obtain prior approval from the AFCD. If they are imported for contained use, prior approval is not required though declaration has to be made on import documents.

The Hong Kong government maintains a Genetically Modified Organisms Register which lists all the importation of living modified organisms that are to be released into the environment. The Register does not show the importation of any cloned animals which are to be released into the environment.

The HKG did not comment on FDA's Risk Assessment on products from cloned animals and their progeny in January 2008. However, in December 2006 when FDA issued three documents on the safety of animal cloning (a draft risk assessment; a proposed risk management plan and a draft guidance for industry), the HKG immediately wrote to ATO enquiring about the U.S. control measures on production/exportation of meat and milk products from cloned animal, and whether any such product has been exported to Hong Kong. It specifically cited FDA's request in the proposed risk management plan for industry's voluntary moratorium on introducing products of cloned animals into commerce.

However, the HKG does not have any immediate plan to change their import policies on food products derived from cloned animals. With regard to cloning animal technology, the HKG has no plans underway to conduct a risk assessment.

b) Labeling and Traceability:

None

c) Trade Barriers:

None

d) Intellectual Property Rights (IPR):

Hong Kong is not considering any legislation to address intellectual property rights for animal biotechnologies.

e) International Treaties/Fora:

Hong Kong participates in World Organization for Animal Health (OIE) as part of the China delegation, but not as a member on its own.

Part G: Marketing

a) Market Acceptance:

We expect that certain legislative Council members, media and consumers group will press the HKG to look into the issue if products of cloned animals are exported to Hong Kong. The HKG may be sensitive to political pressure on this issue. Post believes any new requirement would likely seek to label the food products as cloned as opposed to banning them.

b) Public/Private Opinions:

Currently there are occasional calls for mandatory labeling for GE products by consumer and green groups while there is no mentioning for policy/legislation urgency on importation of cloned animals because the public assume that the latter is not yet an immediate issue.

c) Market Studies:

None

Part H: Capacity Building and Outreach:

a) Activities:

None

b) Strategies and Needs:

Not applicable for the moment